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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,832	01/15/2002	Gregory R. Mundy	432722002612	3485

25225 7590 11/22/2002
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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 11/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,832

Applicant(s)

Mundy et al.

Examiner

Ralph Gitomer

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 5, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25 and 45-70 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25 and 45-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

The IDS received 4/1/02 and the amendment received 8/5/02 have been entered. The references in the IDS have not been considered because they are not found in this file. And no exhibits are present in this file.

In view of the arguments presented, the rejection of record under 35 USC 103 is hereby withdrawn.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25, 45-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7-13 of copending Application No. 09/361,775, now US Patent 6,410,512. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim PSI for the same function but the present application broadly includes additional compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5 Applicant's arguments filed 8/5/02 have been fully considered but they are not persuasive.

Applicants argue that the above rejection will be addressed in the future. Until such time, the rejection is maintained.

10 Claims 25, 45-70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for PSI, does not reasonably provide enablement for ~~the~~ a compound that inhibits proteasomal activity, inhibits the chymotrypsin like activity of the proteasome~~s~~. The specification does not enable
15 any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

On page 27 of the present specification, PSI is defined as N-carbobenzoyl-Ile-Glu-(OtBu)-Ala-Leu-CHO. On page 34 high
20 throughput screening is mentioned but does not state for what the compounds were screened. On page 43 Example 10 shows effects of PSI on subcutaneous tissue of the scalp of mice. Example 11 is directed to cultured skin from mice. Example 12 is directed to inducing anagen in mice with the drug injected into the site of
25 interest directly. Example 13 is directed to topical PSI in

mice. All of the examples include no meaningful or statistically significant data regarding its effects especially as claimed in present claims 64, 68, 70 and others. Please specifically point out in the specification complete written description for all the claimed features.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.
 2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.
 3. Presence of working examples are only for specific substances and extension to other compounds has not been specifically taught or suggested.
 4. The nature of the invention is complex and unpredictable.
 5. State of the prior art indicates that most related substances are not effective for the claimed functions.
 6. Level of predictability of the art is very unpredictable.
 7. Breadth of the claims encompasses an innumerable number of compounds.
 8. The level of one of ordinary skill in this art is variable.
- In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Applicant's arguments filed 8/5/02 have been fully considered but they are not persuasive.

Applicants argue that the specification teaches methods for identifying compounds for the claimed method. PSI increases the number of active hair follicles. Other compounds also increase hair growth.

It is the examiner's position that the present claims are directed to a method of treating, not a method of finding treatments. Only a single compound is disclosed, PSI, for the claimed function and it is unclear how that compound was found nor what compounds were tested.

Claims 25, 45-70 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 25 the compound is described in functional terms only, not what the structure or name of the compound may be which is indefinite.

Applicant's arguments filed 8/5/02 have been fully considered but they are not persuasive.

Applicants argue that functional language is acceptable.

It is the examiner's position that the functional language renders the claims indefinite. One cannot determine the metes and bounds of ~~the~~ a compound that inhibits proteasomal activity~~the~~ as claimed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Mundy (6,410,512 and 6,462,019) are related patents.

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If
10 attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist
15 whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button Patent Electronic Business Center for more information.

Ralph Gitomer

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